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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,426	12/15/2003	David Bebbington	VPI/00-130-06 CON US	3948
27916	7590	10/07/2004	EXAMINER	
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			HABTE, KAHSAY	
			ART UNIT	PAPER NUMBER

1624

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,426

Applicant(s)

BEBBINGTON ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 16, 18, 19, 22, 24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-16, 18-19, 22, 24 and 26-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

1. Claims 1-13, 15-16, 18-19, 22, 24 and 26-29 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 16, there has been recited a method of inhibiting Aurora-2 activity in a patient, but the specification is not enabled for such a scope.

The claim calls for a method of inhibiting Aurora-2 activity in any patient that may or may not need the inhibition of Aurora-2. The specification does not support that.

Note that "patient" covers anyone ill for any reason whatsoever.

3. Claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. In claim 18, there has been recited a method of treating cancer in general but the specification is not enabled for such a scope.

The claim sets forth the treatment of cancer generally. However, there never has been a compound capable of treating cancer generally. There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a “silver bullet” is contrary to our present understanding in oncology. Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body’s cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task.

The enablement rejection in claim 18 also applies to claim 19, because the treatment of cancer selected from melanoma, lymphoma, neuroblastoma, leukemia, colon, breast, kidney, ovary, pancreatic, renal, CNS, cervical, prostate, or gastric tract are also broad and hard to treat diseases. For example, CNS cancer would cover all

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cancers of the central nervous system. There are some types of central nervous system tumors that are more common than others. The most common kind of brain tumor is called astrocytoma. It is a tumor that grows in cells in the brain called astrocytes. Other kinds of brain tumors are medulloblastomas, pineoblastomas, oligodendrogliomas, ependymomas, tumors of neurons and gangliogliomas. There are different kinds of spinal cord tumors e.g. chordoma and meningioma.

Leukemia is kind of cancer that starts in the bone marrow also covers a wide range of cancers. There are different kinds of leukemia. There are kinds that grow fast and kinds that grow very slow e.g. Acute Lymphoblastic Leukemia, Acute Myelogenous Leukemia or AML. A kind of leukemia that grows slow is called Chronic Myelogenous Leukemia or CML.

Note that cancers of gastric tract would cover all cancers of the body the gastrointestinal tract (e.g. mouth, throat, esophagus, stomach, colon, anus, etc.). For example, pharynx cancer is a type of cancer that starts in the throat. Another examples are gastric cancer that starts in the stomach and colon cancers that starts in the intestines. Since the cancers recited in claim 19 are very broad and are different one from the other, the enablement rejection is proper.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ

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609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

4. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most of the diseases recited in claim 24, does not reasonably provide enablement for AIDS-associated dementia, amyotrophic lateral sclerosis (ALS) and Parkinson's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

AIDS-associated dementia is an untreatable disease. No one has been able to treat AIDS associated dementia. The skill level in the art is so low that further research is needed to enable one skilled in the art to treat what is so far untreatable without undue experimentation. To this day, there is no single drug that can be used as a treatment for AIDS-associated dementia.

It has been recited in claim 24 a method of treating amyotrophic lateral sclerosis (ALS), but the specification is not enabled. Amyotrophic lateral sclerosis (ALS) that is a motor neuron disease that is progressive and degenerative. Symptoms may include difficulty swallowing, limb weakness, slurred speech, impaired gait, facial weakness, and muscle

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cramps. Respiration may be affected in the later stages of these diseases. There is no pharmacological treatment for ALS itself.

In claim 24, a method of treating Parkinson's disease has been recited. Parkinson's disease is a neurological disorder that is also characterized by rhythmic muscle tremors, hypokinesia, and muscular rigidity. Dopamine, a hormonelike substance is an important neurotransmitter in both the central and peripheral nervous systems that is currently used as treatment for Parkinsonism. Dopamine is a neurotransmitter involved in the regulation of the central nervous system. The skill level in the art is such low that the only treatments available to this day are drugs that are helpful in regulating Dopamine. Thus, a rejection under 35 U.S.C. 112, first paragraph is proper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15-16, 18-19, 22, 24 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claims 1 and claims dependent thereon are rejected because the term "Heterocyclyl" is indefinite. What is the number and nature of the heteroatoms? Can

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the ring be fused or spiroconnected to another ring, and if so, what kind of ring? Can the ring be bridged? Unsaturated? Cf *In re Wiggins*, 179 USPQ 421, 423.

b. In claim 19, the phrase "cancer of the gastric tract" is not clear. There is no such a cancer. There is a gastric juice or a gastrointestinal tract. It is recommended that applicants amend the claim to read s "gastrointestinal tract" which will overcome the second paragraph rejection.

Conclusion

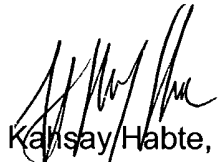
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

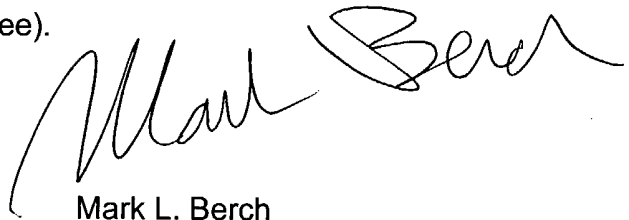
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kaysay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
October 6, 2004